

REMARKS

Claims 123-127, 141, 142 and 149-158 were pending in the present application. By virtue of this response, claims 123, 126, 127, and 153 have been amended. Accordingly, claims 123-127, 141, 142 and 149-158 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Rejections under 35 U.S.C. § 102(b)

Claims 123-127, 141-124 and 149-158 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Testerman et al. (US 5,522,862).

In response, independent claim 123 has been amended to recite “at least one electrode configured to target a diaphragm or phrenic nerve tissue of a patient's body wherein the at least one electrode is configured to deliver electrical stimulation to the diaphragm or phrenic nerve tissue to thereby elicit a diaphragm response”. (Specification, [0038].) Independent claims 126 and 153 have been similarly amended to recite the at least one electrode being configured to target the diaphragm or phrenic nerve tissue (which is in direct communication with the diaphragm) to elicit a diaphragm response.

On the other hand, Testerman et al. shows and describes “stimulation of the musculature of the upper airway in synchrony with the inspiratory phase of the respiratory cycle” and fails to show or describe direct stimulation of the diaphragm or phrenic nerve tissue. (Testerman et al., 5: 13-15.) Rather, “the muscle stimulated is the genioglossus muscle stimulated by a cuff electrode placed around the hypoglossal nerve.” (Testerman et al., 5: 60-62 & Figs. 33-34.)

Electrically stimulating the diaphragm or phrenic nerve tissue to mitigate an obstructive disorder is an entirely different process from electrically stimulating a hypoglossal nerve. The hypoglossal nerve is a cranial nerve and emerges from or enters the skull to primarily supply the muscles of the tongue. (See attached Exhibit A, <http://www.medterms.com/script/main/art.asp?articlekey=7652>.) On the other hand, the diaphragm muscle controls respiration and is itself controlled by the phrenic nerve. (See attached Exhibit B, <http://www.medterms.com/script/main/art.asp?articlekey=2983>.) Thus,

as taught by Testerman et al., the application of electrical stimulation to the hypoglossal nerve affects only the genioglossus muscle to open the airway to the lungs yet does not affect the diaphragm itself to mitigate any obstructive airway disorder, as presently claimed.

However, the application of electrical stimulation to the diaphragm itself or to the phrenic nerve, which in turn controls the diaphragm, does directly affect respiration as the diaphragm itself controls respiration. Thus, applying electrical stimulation to the diaphragm or phrenic nerve cannot be considered equivalent to stimulating the hypoglossal nerve which merely contracts the genioglossus muscle yet does not affect the act of respiration itself.

Therefore, Testerman et al. cannot anticipate independent claims 123, 126, and 153. The dependent claims depend ultimately from claims 123, 126, and 153 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 USC §102(b).

Rejections under 35 U.S.C. § 102(e)

Claims 123-127, 141-142 and 149-158 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Ignagni et al. (US Patent Publication 20050021102 A1)

In response, independent claim 123 has been amended to recite “a stimulator configured to deliver a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to sensed respiration due to phrenic nerve activity detected internally within the patient’s body”. (Specification, [0012].) Independent claims 126 and 153 have been similarly amended to recite delivering a stimulation signal to the diaphragm or phrenic nerve tissue through the at least one electrode in response to phrenic nerve activity which is detected within the patient’s body via an internally implanted sensor.

On the other hand, Ignagni et al. shows and describes a device which is configured to deliver electrical stimulation on a continuous or periodic basis which is preset. (Ignagni et al., [0030].) Ignagni et al. only describes utilizing physiologic activity where an air flow sensor external to the body can be provided with an external mechanical ventilator for detecting the inspiratory or expiratory air flow. (Ignagni et al., [0035] & Fig. 4.) However, the sensing of air flow is an entirely different mode of sensing from phrenic nerve activity in mechanism and principle. Moreover, the air flow sensor is a sensor which is necessarily

positioned external to the patient's body and cannot be said to be internally within the patient's body, as presently claimed.

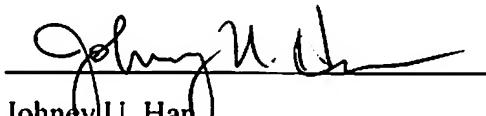
Therefore, Ignagni et al. cannot anticipate independent claims 123, 126, and 153. The dependent claims depend ultimately from claims 123, 126, and 153 and are patentable for at least the same reasons. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejections under 35 USC §102(e).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **RMXLNZ00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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EXHIBIT A

10/16/2008

Hypoglossal nerve definition - Medici...

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Source: <http://www.medterms.com>

MedTerms is the Medical Dictionary of MedicineNet.com

Definition of Hypoglossal nerve

Hypoglossal nerve: The hypoglossal nerve is the twelfth cranial nerve. The twelve cranial nerves, the hypoglossal nerve included, emerge from or enter the skull (the cranium), as opposed to the spinal nerves which emerge from the vertebral column.

The hypoglossal nerve supplies the muscles of the tongue. (The Greek "hypo-", under and "-glossal" from A "glossa", the tongue = under the tongue).

Paralysis of the hypoglossal nerve affects the tongue. It impairs speech (it sounds thick) and causes the tongue to deviate toward the paralyzed side. In time, the tongue diminishes in size (atrophies).

Last Editorial Review: 12/1/1998 5:12:00 PM

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EXHIBIT B

10/16/2008

Diaphragm (muscle) definition - Medi...

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Source: <http://www.medterms.com>

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Definition of Diaphragm (muscle)

Diaphragm (muscle): The muscle that separates the chest (thoracic) cavity from the abdomen. The diaphragm is the main muscle of respiration. Contraction of the diaphragm muscle expands the lungs during inspiration when one is breathing air in. We rely heavily on the diaphragm for our respiratory function so that when the diaphragm is impaired, it can compromise our breathing. The nerve that controls the diaphragm is the phrenic nerve, which originates much high (at C3-C5). During development the diaphragm moves down and drags the phrenic nerve with it.

Last Editorial Review: 7/18/2004

Common Misspellings: diaphram (muscle)

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